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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,590

04/08/2004

Paul Albert Sagel

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27752

7590

07/13/2006

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/820,590	Applicant(s) SAGEL ET AL.	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 13-16 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on April 8, 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to a whitening compositions, classified in class 433, subclass 216.
- II. Claims 14-17, drawn to a method of manufacturing a whitening composition, classified in class 424, subclass 401.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the compositions can be made by dissolving the polymers in the same mixture.

Because these inventions are independent or distinct for the reasons given above, have acquired a separate status in the art in view of their different classification and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

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All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Angela Haughey on July 6, 2006 a provisional election was made with traverse to prosecute the invention of I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims

Claim Objection

Claim 1 is objected to because of the following informalities: the term "polyethelene" should read "polyethylene". Appropriate correction is required.

Claim Rejections - 35 USC § 102 – Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1, 3-6, 8 and 11-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al. (2003/0194382).

Chang teaches multi-layer patches for teeth whitening. The whitening agents that may be used include hydrogen peroxide as recited in claim 11. The polymers that may be used to make the adhesive layer or the layer comprising the whitening agent include hydrophilic glass polymers such as polyvinyl pyrrolidone, polyquaternium-11, polyquaternium-39 and polyvinyl pyrrolidone-vinyl acetate copolymer (PVP/VA copolymer), which have good compatibility with peroxide and are easily soluble in water, ethanol or mixtures thereof, encompassing claim 12. They also have good solubility in organic solvents. Polyethylene oxide may also be used in the compositions and is not

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soluble in ethanol but easily soluble in water or other organic solvents and has good compatibility with peroxide (paragraph 0041). Another polymer that may be used is polyvinyl alcohol (see example 1). The polymers may be used alone or in mixtures. In one of the compositions polyvinyl alcohol comprised 5% of the compositions and the other polymer comprised 12% of the compositions (paragraph 0079), encompassing claim 3. Water comprised about 70 of the same composition (paragraph 0079). The compositions also include plasticizers since some polymers have a poor flexibility. Suitable plasticizers added include polypropylene glycol, glycerin, and polyethylene glycol, encompassing claim 6. The plasticizers are included at levels ranging from 3% to 7% of the active layer composition based on the examples, encompassing claim 5. The patches also comprise a backing layer. The layers encompass claim 8. The reference anticipates the instant claims insofar as it teaches whitening composition product comprising a backing layer and a tooth whitening composition comprising polyvinyl alcohol, polyethylene oxide, water and a plasticizer.

2) Claims 1-8 and 11-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Godby et al. (US 2002/0187181).

Godbey et al. teach delivery systems comprising a water-soluble polymeric carrier, and adhesive, one or more active agents and a support layer. The active agent may be incorporated into either one or both of the carrier and the adhesive compositions (paragraph 0008). When the active agent, e.g., whitening agent, is in both the adhesive and carrier, the two together encompass the whitening composition. The

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polymers that may be used as carriers include polyvinyl alcohol, which is the one of the preferred polymers, polyoxyalkylenes, which encompasses polyethylene oxide, and mixtures thereof (paragraph 0024). The advantage of using polymers of polyvinyl alcohols to prepare the carrier film is that the film may, as a result of its low oxygen permeability, provide protection to oxygen sensitive materials (paragraph 0025). The polyvinyl alcohol used in the examples was 87% hydrolyzed encompassing claim 7. The amount of polyvinyl alcohol used in the compositions ranges from 30 to 35% and is dissolved in water, which makes up about 65% of the carrier composition, encompassing claim 3. The amount of water used in the adhesive and carrier compositions encompass claim 4. Plasticizers that may be used include polyethylene glycol, water and mixtures comprising 1 to 50% of the carrier. Adhesives used in the compositions include poly(ethylene oxide) (paragraph 0036). Polymers suitable for use in the adhesive may be an uncrosslinked polymer or mixture of polymers with an overall number average molecular weight between 10,000 and 100,000 Daltons. Such polymers provide a good balance of cohesive strength and water-solubility. The adhesive composition of the device of the present invention may include the polymer in a relative amount of from about 10 to about 60 weight percent of the adhesive composition, encompassing claim 2. The adhesive compositions may include plasticizers up to 80% and water up to 60% (paragraph 0039). The device may be used to deliver whitening agents including hydrogen peroxide, encompassing claim 11. The support layer may be a multilayered laminate (paragraph 0057), encompassing claim 8. The reference anticipates the instant claims insofar as it teaches whitening composition

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product comprising a backing layer and a tooth whitening composition comprising polyvinyl alcohol, polyethylene oxide, water and a plasticizer.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 2, 7 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (2003/0194382).

Chang et al. is discussed above. The reference discloses polymers in teeth whitening compositions. The polymers that are used include polyvinyl alcohol and polyethylene oxides such as Polyox which is the trade name used by DOW Chemicals. It is well known that the molecular weights of the polyethylene oxides typically range from 100,000 to 8,000,000¹. Polyvinyl alcohols come in several different states ranging from partly hydrolyzed to fully hydrolyzed. It is well known that the degree of hydrolysis determines the polymer properties such as adhesiveness and viscosity². The reference differs from the instant claims insofar as it does not specifically teach the specific molecular weight of the polyethylene oxides used or that a combination of polyethylene oxides was used.

Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to have chosen the polyethylene oxide with a certain molecular weight incorporated at the optimum weight percent and polyvinyl alcohol with a certain degree of hydrolysis to obtain the desired properties of the composition, as supported by case law.

¹ Dow Chemicals page 1

2) Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey et al. (US 2002/0187181) in view of Xu et al. (US 2002/0187111).

The primary reference Godbey et al. is discussed above. It teaches polymers suitable for use in the adhesive may be an uncrosslinked polymer or mixture of polymers with an overall number average molecular weight between 10,000 and 100,000 Daltons. Such polymers provide a good balance of cohesive strength and water-solubility. The reference also teaches polyoxyalkylenes may be mixed with polymer such as polyvinyl alcohol in the carrier compositions. The reference differs from the instant claims insofar as it does not teach specifically mixtures and the molecular weight of the poly(ethylene oxide) polymers.

Xu et al. teach whitening strips comprising polyethylene oxide. The whitening agents include hydrogen peroxide (paragraph 0011). The ethylene oxide polymer comprises 50 to 95% of the composition (paragraph 0012). The polymer is hydratable and varying the properties of the polymer can control the release of the whitening agent. The properties of films are varied by varying film thickness and using a mixture of different molecular weight polyethylene oxide polymers (100,000 – 1,500,000 Daltons) (paragraph 0008-0010). The reference differs from the instant claims insofar as it does not teach a second polymer such as polyvinyl alcohol.

It would have been obvious to one of ordinary skill in the art to have used the polyethylene oxides of different molecular weights and mixtures in the compositions of the primary reference motivated by the desire to make an adhesive layer that provides a

² DC Chemical Co., Ltd. Pages 4-5.

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good balance of cohesive strength, water-solubility and the desired rate of release of the whitening agent, as disclosed by the secondary reference.

Obvious- Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/936,756. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are coextensive insofar as they both teach whitening products comprising a barrier layer and a composition comprising two polymers, a whitening agent, water and a plasticizer. The claims of the copending application are broader than the instant claims insofar as the

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instant claims define the two polymers in the independent claim whereas the copending claims define the first polymer in the dependent claims. The first polymer is defined as a polyethylene oxide and the second polymer a polyvinyl alcohol, making the claims coextensive over one another in the manner outlined in the cited precedent (In re Vogel, etc.).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-12 are rejected.

Claim 1 is objected.

Claims 13-16 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614



Frederick Krass
Primary Examiner
Art Unit 1614

